



Practitioner's Docket No. U 014450-3

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Rama MUKHERJEE, et al.

Application No.: 10/627,398

Filed: July 25, 2003

For: CARDIOPROTECTIVE AGENTS

Group No.: 1617

Examiner: Chong, Yong Soo

**Commissioner for Patents**

**P. O. Box 1450**

**Alexandria, VA 22313-1450**

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
BEFORE MAILING DATE OF EITHER A FINAL ACTION  
OR NOTICE OF ALLOWANCE (37 C.F.R. 1.97(c))**

*NOTE: 37 C.F.R. 1.97: "(c) An information disclosure statement shall be considered by the Office if filed after the period specified in paragraph (b) of this section, provided that the information disclosure statement is filed before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application, and it is accompanied by one of:*

*(1) The statement specified in paragraph (e) of this section; or*

*(2) The fee set forth in § 1.17(p)."*

*NOTE: "If a final action or notice of allowance is mailed in an application and later withdrawn, the application will be considered as not having had a final action or notice of allowance mailed for purposes of considering an information disclosure statement." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***

*(When using Express Mail, the Express Mail label number is **mandatory**;  
Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

**37 C.F.R. 1.8(a)**

**37 C.F.R. 1.10\* (Preferred)**

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**TRANSMISSION**

☐ transmitted by facsimile to the Patent and Trademark Office to **(571)-273-8300**

Date: February 15, 2006

  
Signature

JANET I. CORD

(type or print name of person certifying)

02/21/2006 SHASSEN1 00000031 10627398

02 FC:1806

180.00 OP

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

*NOTE: 37 C.F.R. § 1.704(d): "A paper containing only an information disclosure statement in compliance with §§ 1.97*

and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section if it is accompanied by a statement that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement. This thirty-day period is not extendable."

**NOTE:** "If information submitted during the period set forth in 37 C.F.R. 1.97(c) with a certification is used in a new ground of rejection on unamended claims, the next Office action will not be made final since in this situation it is clear that applicant has submitted the information to the office promptly after it has become known and the information is being submitted prior to a final determination on patentability by the Office. However, the information submitted with a certification can be used in a new ground of rejection and the next Office action made final, [i]f the new ground of rejection was necessitated by amendment of the application by applicant. Where the information is submitted during this period with a fee, the examiner may use the information submitted, e.g., printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP 706.07(a). If a new ground of rejection is introduced that is neither necessitated by an amendment to the claims nor based on the information submitted with the fee set forth in 37 C.F.R. 1.17(p), the Office action shall not be made final. Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63). But see § 103(b) and (c), limited suspension of action in a continued prosecution application (CPA) filed under § 1.53(d) and in a request for continued examination (RCE) under § 1.114.

**WARNING:** No extension of time can be had under 37 C.F.R. 1.136(a) or (b) for filing an IDS. 37 C.F.R. 1.97(f).

### TIME OF TRANSMITTAL OF ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

1. The information disclosure statement transmitted herewith is being filed **after** three months of the filing date of this national application or the date of entry of the national stage as set forth in § 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but **before** the mailing date of either:

- (1) a final action under § 1.113 or
- (2) a notice of allowance under § 1.311,

whichever occurs first.

### STATEMENT OR FEE

2. Accompanying this transmittal is  
(check either A or B below)

A. ☐ a statement as specified in 37 C.F.R. 1.97(e).

OR

B. ☒ the fee set forth in 37 C.F.R. 1.17(p) for submission of an information disclosure statement under § 1.97(c). (\$180.00).

### METHOD OF PAYMENT OF FEE

3. ☒ Attached is a check in the amount of \$ 180.00.

[ ] Charge Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_.  
A duplicate of this request is attached.

If any additional **or lesser** fees are due, please charge **or refund deposit** Account 12-0425.

  
SIGNATURE OF PRACTITIONER

Reg. No. 33,778

JANET I. CORD  
(type or print name of practitioner)

Tel. No.: (212)708-1935

\_\_\_\_\_  
P.O. Address

Customer No.:

\_\_\_\_\_  
c/o Ladas & Parry LLP  
26 West 61<sup>st</sup> Street  
New York, N.Y. 10023



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Rama

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Attorney Docket No.: U 014450-3

Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

We draw the attention of the Examiner to the attached English-language version of an Action or International-type Search Report from a foreign office in respect of counterpart PCT Application No. IN2004/00216 that indicates the degree of relevance found by the foreign office. The Action or Search Report makes consideration of any non-English art required. MPEP 609.

**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***

*(When using Express Mail, the Express Mail label number is mandatory;  
Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

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**37 C.F.R. 1.8(a)**

- ☒ with sufficient postage as first class mail.

**37 C.F.R. 1.10\***

- ☐ as "Express Mail Post Office to Addressee"  
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- ☐ transmitted by facsimile to the Patent and Trademark Office, to (571)-273-8300.

Date: February 15, 2006

Signature

JANET CORD  
(type or print name of person certifying)

**\*WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).  
"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

References discussed in this response are also being filed with this Information Disclosure Statement.

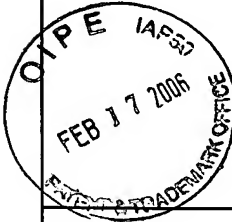
Form PTO-1449 is also attached with reference copies (first page only for U.S. patent publications)(first page only for U.S. patent publications).

Respectfully submitted,

A handwritten signature in black ink, consisting of a large, stylized 'J' and 'C' that are connected and looped together. The signature is written above a horizontal line.

---

Janet I. Cord  
c/o Ladas & Parry LLP  
26 West 61st Street  
New York, New York 10023  
Reg. No. 33,778, (212-708-1935)

FORM PTO-1449		U. S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.		SERIAL NO.	
				U 014450-3		10/627,398	
		INFORMATION DISCLOSURE STATEMENT BY APPLICANT					
		(Use several sheets if necessary)					
		APPLICANT					
		Rama MUKHERJEE, et al.					
				FILING DATE		GROUP	
				July 25, 2003		1617	
U.S. PATENT DOCUMENTS							
EXAMINER INITIALS	REFERENCE DESIGNATION	DOCUMENT NUMBER	DATE	NAME		FILING DATE IF APPROPRIATE	
	AA	2003/105318 A	06/2003	OGOZALEK KRISTINE et al			
	AB						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION		
					YES	NO	
	AC	02/22573 A	03/2002	WO			
	AD	01/49286 A	07/2001	WO			
	AE	2004/045509 A	6/2004	WO			
	AF	2003/105318	6/2003	WO			
OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)							
	AG	DATABASE CA "ONLINE CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; VINOGRADOV, V.M. ET AL: "Effect of antioxidants on the resistance to hypoxia, and some aspects of energy metabolism" XP002311445 Retrieved from STN Database accession no. 1970:53551 abstract & MATER. SIMP. "VYSOKOGOR'E KRASNAYA KROV' KONF. "VYSOKOGOR'E LEK.", 173-4. EDITOR(S): ALIEV, M.A. PUBLISHER: IZD. "ILIM", FRUNZE, USSR. CODEN:21XFAX, 1968					
	AH	DATABASE CA "ONLINE CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; ROGOVA, L.S. ET AL: "Antiarrhythmic properties of some indole alkylamines" XP002271167 retrieved from STN Database accessionno. 70:2017 abstract & BYULLETEN EKSPERIMENTAL 'NOI BIOLOGII I MEDITSINY (1968), 66(10), 58-60, 1968					
	AI	DATABASE WPI Week 197909 12 May 1978 (1978-05-12) Derwent Publications Ltd., London, GB;AN 1979-17341B KRASNYKU ET AL.: "5-Methoxytryptamine pharmaceutical - used as radiation sickness protective agent' & SU 227 537 A (ZHEREBCHENKO P.G.) 12 MAY 1978 (1978-05-12) abstract					
	AJ	ABD EL-AZIZ M A ET AL: "potential protective role of angiotensin converting enzyme inhibitors captopril and enalapril against adriamycin-induced acute cardiac and hepatic toxicity in rats" JOURNAL OF APPLIED TOXICOLOGY, vol. 21, no. 6, November 2001 (2001-11), pages 469-473, XP008040546 ISSN: 0260-437X cited in the application					
	AK	HARA M ET AL: Administration of melatonin and related indoles prevents exercised-induced cellular oxidative changes in rats." BIOLOGICAL SIGNALS, (1997 MAR-APR) 6 (2) 90-100., March 1997 (1997-03), XP008027668 abstract					
EXAMINER				DATE CONSIDERED			
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

FORM PTO-1449 U. S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use several sheets if necessary)		ATTY. DOCKET NO.		SERIAL NO.	
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	AA				
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FOREIGN PATENT DOCUMENTS					
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION
					YES NO
	AC				
	AD				
	AE				
	AF				
OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)					
	AG	T.M. Suter, et al., ANNALS OF ONCOLOGY, "Detection of anthracycline-induced cardiotoxicity: is there light at the end of the tunnel?", 13:647-649 (2002)			
	AH	Van Vleet, et al., AMERICAN JOURNAL OF PATHOLOGY; "Cardiac Disease Induced by Chronic Adriamycin Administration in Dogs and an Evaluation of Vitamin E and Selenium as Cardioprotectants"; Vol. 99, No. 1, pp. 13-24 (1980)			
	AI	Breed, et al.; DEPT. OF ONCOLOGY, FREE UNIVERSITY HOSPITAL AND NETHERLANDS CANCER INSTITUTE DE DOLLELAAN, AMSTERDAM; "Failure of the Antioxidant Vitamin E to Protect against Adriamycin-induced Cardiotoxicity in the Rabbit"; Vol. 40, pp. 2033-2038 (1980)			
	AJ	Myers, et al.; SEMINARS IN ONCOLOGY; "A Radomized Controlled Trial Assessing the Prevention of Doxorubicin Cardiomyopathy by N-Acetylcysteine"; Vol. 10, No.1, Supp. 1, pp.53-55 (1983)			
	AK	Herman, et al.; CANCER RESEARCH; "Comparison of the Effectiveness of (±)-1,2-Bis(3,5-dioxopiperazinyl-1-4)propane (ICRF-187) and N-Acetylcysteine in Preventing Chronic Doxorubicin Cardiotoxicity in Beagles"; Vol.45, pp. 276-281(1985)			
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	AD				
	AE				
	AF				
OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)					
	AG	Xu, et al.; JOURNAL OF PINEAL RESEARCH; "Melatonin protects cardiac toxicity of doxorubicin in rat"; Vol. 31, pp. 301-307 (2001)			
	AH	Xu, et al.; LIFE SCIENCES; "Effects by doxorubicin on the myocardium are mediated by oxygen free radicals"; Vol. 68, pp. 889-901 (2001)			
	AI	Luo, et al.; BIOCHIMICA ET BIOPHYSICA ACTA; "Doxorubicin-induced acute changes in cytotoxic aldehydes, antioxidant status and cardiac function in the rat"; pp. 45-52 (1997) XP004e77513			
	AJ	Gillum, et al.; AMERICAN HEART JOURNAL; "International diagnostic criteria for acute myocardial infarction and acute stroke"; pp. 150-158 (1984)			
	AK	Christenson, et al.; CLINICAL CHEMISTRY; "Biochemical markers of the acute coronary syndromes", Vol. 44 No. 8(b), pp.1855-1864 (1998)			
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